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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,158	08/30/2005	Akira Nakagawara	7388/84325	2186

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EXAMINER
AEDER, SEAN E

ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
12/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,158	NAKAGAWARA ET AL.	
	Examiner	Art Unit	
	Sean E. Aeder	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/9/06; 7/20/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

The response filed on 11/15/07 to the restriction requirement of 10/18/07 has been received. Applicant has elected the species SEQ ID NO:1 for examination with traverse. The traversal is based on a request that SEQ ID NO:175 and SEQ ID NO:176 should be examined with instant SEQ ID NO:1 because SEQ ID NO:175 and SEQ ID NO:176 are either part SEQ ID NO:1 or part of a complement of SEQ ID NO:1. This request is granted and the species SEQ ID NO:175 and SEQ ID NO:176 have been rejoined.

Claims 1-16 are pending and are currently under consideration.

Specification

The specification is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see line 23 on page 40). Applicant is required to delete all embedded hyperlinks and/or other form of browser-executable codes. See MPEP § 608.01.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-9, 14, and 16 are rejected under 35 U.S.C. 101 because claims 1-9, 14, and 16, as written, do not sufficiently distinguish over nucleic acids, nucleic acid probes,

and primers as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claim 11 recites a method for determining stage 4s neuroblastoma comprising detecting the presence or absence of a nucleic acid comprising SEQ ID NO:1; however, claim 11 does not recite what type of result is indicative of a determination of stage 4s neuroblastoma. The omitted steps are: correlating a specific result to a determination of stage 4s neuroblastoma.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 5-10, and 12-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the claims are inclusive of: (1) a genus of nucleic acids complementary to SEQ ID NO:1 (see claim 3); (2) a genus of nucleic acids comprising "partial length" fragments of SEQ ID NO1 (see claims 5-7); (3) a genus of nucleic acids complementary to a nucleic acid comprising a partial length of full length SEQ ID NO:1 (see claims 5-7); (4) a genus of nucleic acids capable of hybridizing to nucleic acids comprising "partial length" fragments of SEQ ID NO1 (see claims 5-7); (5) a genus of nucleic acids capable of hybridizing to nucleic acids complementary to a nucleic acid comprising a partial length of full length SEQ ID NO:1 (see claims 5-7); (6) a genus of DNA complementary to DNA comprising SEQ ID NO:175 or SEQ ID NO:176 (see claims 8-10 and 15); (7) a genus of DNA capable of hybridizing to DNA complementary to DNA comprising SEQ ID NO:175 or SEQ ID NO:176 (see claims 8-10 and 15); (8) a genus of nucleic acids comprising partial lengths of nucleic acids comprising SEQ ID NO:1 (see claim 12); (9) a genus of nucleic acids comprising “a” nucleic acid sequence set forth in one of SEQ ID NO:175 or SEQ ID NO:175 (see claim 13); and (10) a genus of nucleic acids capable of hybridizing to

nucleic acids complementary to SEQ ID NO:1 under stringent hybridization conditions (see claim 14).

It is noted that claims drawn to nucleic acids complementary to a SEQ ID NO encompass partial complements sharing as few as one nucleotide with a sequence complement to said SEQ ID NO. Further, nucleic acids comprising "partial length" sequences of SEQ ID NOs read on nucleic acids comprising fragments of any size of said SEQ ID NOs. Clearly, there is great variation in genera encompassing partial complements and/or partial lengths of a particular SEQ ID NO. Further, genera encompassing sequences that would hybridize to partial complements and/or partial lengths of a particular SEQ ID NO are especially broad. Further, nucleic acids drawn to sequences comprising "a" nucleic acid sequence set forth in a particular SEQ ID NO (rather than "the" nucleic acid sequence set forth in a particular SEQ ID NO) encompass sequences sharing as few as two consecutive nucleotides with said SEQ ID NO.

The written description in this case sets forth polynucleotides comprising SEQ ID NO:1 and the full complement thereof, polynucleotides comprising SEQ ID NO:175 and the full complement thereof, and polynucleotides comprising SEQ ID NO:176 and the full complement thereof. However, the specification does not disclose, and the art does not teach, the genera as broadly encompassed by the claims.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common to that genus that "constitute a substantial portion of the

genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus."

The court has since clarified that this standard applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., F.3d, 2004 WL 260813, at *9 (Fed.Cir.Feb. 13, 2004). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genera. That is, the specification provides neither a representative number of sequences that encompass the genera nor does it provide a description of structural features that are common to the genera. Further, in regards to genera encompassing variants, such as partial complements and sequences that hybridize to partial complements, Applicant is directed to Example 13 of the Synopsis of Application of Written Description Guidelines (http://www.uspto.gov/web/menu/written.pdf), which addresses claims drawn to a genus of polypeptide variants. Example 13 states that even when a specification discloses that changes which produce variants are routinely done in the art, the specification and the claims do not provide any guidance as to precisely what changes should be made. Structural features that could distinguish the compounds of the claimed genus from others not encompassed by the genus are missing from the disclosure. No common structural attributes identify the members of

the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is needed. Since the disclosure fails to describe common attributes or characteristics that identify members of the genera, and because the genera are highly variant, the disclosure of SEQ ID NO:1, SEQ ID NO:175, and SEQ ID NO:176 is insufficient to describe the genera. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genera as broadly claimed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). The skilled artisan cannot envision the detailed chemical structure of the encompassed genera, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolation. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim 11 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for determining whether a subject with a neuroblastoma has stage 4s neuroblastoma comprising detecting the presence or absence of a nucleic acid comprising SEQ ID NO:1 in a clinical tissue sample of neuroblastoma from said subject wherein the presence of said nucleic acid indicates that said subject has stage 4s neuroblastoma, **the specification does not reasonably provide enablement for** a method for determining stage 4s neuroblastoma comprising detecting the presence or absence of a nucleic acid comprising any sequence selected from the group consisting of SEQ ID NO:1-14 in a clinical tissue sample of neuroblastoma wherein both the presence and absence of said nucleic acid indicates the presence of stage 4s neuroblastoma. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in *Ex parte* Forman, 230 USPQ 546 (BPAI 1986). They

include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The instant claims broadly encompass a method for determining stage 4s neuroblastoma comprising detecting the presence or absence of a nucleic acid comprising any sequence selected from the group consisting of SEQ ID NO:1-14 in a clinical tissue sample of neuroblastoma wherein both the presence and absence of said nucleic acid indicates the presence of stage 4s neuroblastoma. This includes contradictory methods wherein both the presence and absence of a sequence indicates the presence of stage 4s neuroblastoma.

The specification teaches a method for determining whether a subject with a neuroblastoma has stage 4s neuroblastoma comprising detecting the presence or absence of a nucleic acid comprising SEQ ID NO:1 in a clinical tissue sample of neuroblastoma from said subject wherein the presence of said nucleic acid indicates that said subject has stage 4s neuroblastoma (see pages 22-24, in particular). The specification further teaches that SEQ ID NOs:2-14 are *not* either exclusively present or exclusively absent in stage 4s neuroblastoma (see pages 14-23 and Table 1, in particular). Further, the specification provides evidence that SEQ ID NO:1 is not exclusively absent in stage 4s neuroblastoma. Therefore, as claimed, the mere presence of absence of SEQ ID NOs:2-14 would not allow one to determine stage 4s

neuroblastoma. Further, as claimed, one would not determine that a sample comprises stage 4s neuroblastoma in light of determining an absence of SEQ ID NO:1.

The state of the prior art dictates that if the presence or absence of a molecule such as SEQ ID NO:1 is to be used as a surrogate for a particular disease state (such as stage 4s neuroblastoma), said particular disease state must be identified with the presence or absence of said molecule. For example, Tockman et al (Cancer Res., 1992, 52:2711s-2718s) teach considerations necessary in bringing a cancer biomarker (intermediate end point marker) to successful application. Tockman et al teaches that prior to the successful application of newly described markers, research must validate the markers against acknowledged disease end points, establish quantitative criteria for marker presence/absence and confirm marker predictive value in prospective population trials (see abstract). Therefore, absent evidence of the presence or absence of said molecule with a particular diseased state, one of skill in the art would not be able to predictably use the presence or absence of said molecule to diagnose said particular diseased state without undue experimentation.

The level of unpredictability for using the mere presence or absence of a particular molecule to detect any disease state is quite high. Since neither the specification nor the prior art provide evidence of both the presence and absence of SEQ ID NOs:1-14 in a neuroblastoma indicates that said neuroblastoma is a 4s neuroblastoma, a practitioner wishing to practice the claimed invention would be required to provide extensive experimentation to demonstrate such an association. Such experimentation would in itself be inventive.

One cannot extrapolate the teachings of the specification to the scope of the claims because the claims are broadly drawn to a method for determining stage 4s neuroblastoma comprising detecting the presence or absence of a nucleic acid comprising any sequence selected from the group consisting of SEQ ID NO:1-14 in a clinical tissue sample of neuroblastoma wherein both the presence and absence of said nucleic acid indicates the presence of stage 4s neuroblastoma, and Applicant has not enabled said method because it has not been shown that both the presence and absence of SEQ ID NOs:1-14 in a neuroblastoma indicates that said neuroblastoma is a 4s neuroblastoma.

In view of the teachings above and the lack of guidance, workable examples and or exemplification in the specification, it would require undue experimentation by one of skill in the art to determine with any predictability, that the method would function as claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 3, 5-10, and 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Rehman et al (Nucleic Acids Research, January 1999, 27(2):649-655).

Claim 3 is broadly drawn to a nucleic acid complementary to SEQ ID NO:1. It is noted that polynucleotides comprising as few as one nucleic acid complementary to SEQ ID NO:1 are "complementary" to SEQ ID NO:1. Claims 5-6 encompass nucleic acids comprising a partial length of SEQ ID NO:1, a nucleic acid complementary to nucleic acids comprising a partial length of SEQ ID NO:1, nucleic acids capable of hybridizing under stringent conditions to a nucleic acid comprising a partial or the full length of SEQ ID NO:1, and nucleic acids complementary to nucleic acids capable of hybridizing under stringent conditions to a nucleic acid comprising a partial or the full length of SEQ ID NO:1. Claim 7 is drawn to a diagnostic agent for stage 4s neuroblastoma comprising as the active ingredient: nucleic acids comprising a partial length of SEQ ID NO:1, a nucleic acid complementary to nucleic acids comprising a partial length of SEQ ID NO:1, nucleic acids capable of hybridizing under stringent conditions to a nucleic acid comprising a partial or the full length of SEQ ID NO:1, or nucleic acids complementary to nucleic acids capable of hybridizing under stringent conditions to a nucleic acid comprising a partial or the full length of SEQ ID NO:1. Claims 8-9 are drawn to a primer containing a DNA complementary to SEQ ID NO:175, a DNA complementary to SEQ ID NO:176, a DNA capable of hybridizing under stringent conditions to a DNA complementary to SEQ ID NO:175, and a DNA capable of hybridizing under stringent conditions to a DNA complementary to SEQ ID NO:176. It is

noted that polynucleotides comprising as few as one nucleic acid complementary to SEQ ID NO:175 or 176 is "complementary" to SEQ ID NO:175 or SEQ ID NO:176, in particular. Further, as SEQ ID NO:175 and SEQ ID NO:176 comprise at least one of each possible nucleic acid, every polynucleotide imaginable is complementary to SEQ ID NO:175 and SEQ ID NO:176. Claim 10 is drawn to a diagnostic kit comprising a pair of primers wherein the pair of primers are selected from a group of primers consisting of a primer containing a DNA complementary to SEQ ID NO:175, a DNA complementary to SEQ ID NO:176, a DNA capable of hybridizing under stringent conditions to a DNA complementary to SEQ ID NO:175, and a DNA capable of hybridizing under stringent conditions to a DNA complementary to SEQ ID NO:176. Claim 12 is drawn to a nucleic acid microarray comprising a solid phase support and a combination of plural nucleic acids each comprising a partial length of SEQ ID NO:1 on the solid phase support. Claim 13 is drawn to a nucleic acid microarray comprising a solid phase support and a combination of plural nucleic acids each comprising a nucleic acid sequence set forth in one of SEQ I DNO:175 or SEQ ID NO:176 immobilized on the solid phase support. As stated above, nucleic acids drawn to sequences comprising "a" nucleic acid sequence set forth in a particular SEQ ID NO (rather than "the" nucleic acid sequence of a particular SEQ ID NO) encompass sequences sharing as few as two consecutive nucleotides with said SEQ ID NO. Claim 14 is drawn to a nucleic acid capable of hybridizing to a nucleic acid complementary to SEQ ID NO:1. Claim 15 is drawn to a diagnostic kit for stage 4s neuroblastoma comprising one pair of primers containing a DNA complementary to SEQ ID NO:175, a DNA complementary to SEQ ID NO:176, a

DNA capable of hybridizing under stringent conditions to a DNA complementary to SEQ ID NO:175, and a DNA capable of hybridizing under stringent conditions to a DNA complementary to SEQ ID NO:176.

Rehman et al teaches the following polynucleotides (see right column on page 650):

Probe 1: CAGAATCGTTAGTTGATGGGG

Probe 2: AATCCAAAACGGCAGAAG

Probe 3: GTTGCCCGTCTCGCTGGTGAAA

Probes 1-3 are complementary to instant SEQ ID NO:1, as probes 1-3 comprise partial compliments to instant SEQ ID NO:1. Further, each of probes 1-3 are capable of hybridizing to a nucleic acid complementary to SEQ ID NO:1, comprise a partial length of SEQ ID NO:1, a nucleic acid complementary to nucleic acids comprising a partial length of SEQ ID NO:1, nucleic acids capable of hybridizing under stringent conditions to a nucleic acid comprising a partial or the full length of SEQ ID NO:1, and nucleic acids complementary to nucleic acids capable of hybridizing under stringent conditions to a nucleic acid comprising a partial or the full length of SEQ ID NO:1. Further, each of probes 1-3 comprise a primer containing a DNA complementary to SEQ ID NO:175, a DNA complementary to SEQ ID NO:176, a DNA capable of hybridizing under stringent conditions to a DNA complementary to SEQ ID NO:175, and a DNA capable of hybridizing under stringent conditions to a DNA complementary to SEQ ID NO:176. Further, Rehman et al teaches a kit comprising probes 1-3 that comprises a pair of primers wherein the pair of primers are selected from a group of primers consisting of a

primer containing a DNA complementary to SEQ ID NO:175, a DNA complementary to SEQ ID NO:176, a DNA capable of hybridizing under stringent conditions to a DNA complementary to SEQ ID NO:175, and a DNA capable of hybridizing under stringent conditions to a DNA complementary to SEQ ID NO:176 (right column of page 650, in particular). Further, the kit taught by Rehman et al is a nucleic acid microarray comprising a solid phase support and a combination of plural nucleic acids each comprising a partial length of SEQ ID NO:1 on the solid phase support (right column of page 650, in particular). Further, the kit taught by Rehman et al is a nucleic acid microarray comprising a solid phase support and a combination of plural nucleic acids each comprising "a" nucleic acid sequence set forth in one of SEQ I DNO:175 or SEQ ID NO:176 immobilized on the solid phase support (right column of page 650, in particular). Further, the kit taught by Rehman et al comprises one pair of primers containing a DNA complementary to SEQ ID NO:175, a DNA complementary to SEQ ID NO:176, a DNA capable of hybridizing under stringent conditions to a DNA complementary to SEQ ID NO:175, and a DNA capable of hybridizing under stringent conditions to a DNA complementary to SEQ ID NO:176.

Further, it is noted that claims 7, 10, and 15 appear to contain statements reciting purpose or intended use. It is noted that statements of intended purposes or uses are not considered limitations because they merely state an intended use of the invention rather than any distinct definition of any of the claimed invention's limitations (see Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999)). Thus, recitation of statements describing the claimed product as an

active ingredient of a diagnostic agent for stage 4s neuroblastoma, a diagnostic kit, and a diagnostic kit for stage 4s neuroblastoma are not given patentable weight and are not limitations to the claims.

Claims 3-9 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Wang et al (US 2004/0181048 A1; filed 8/8/01).

Claim 3 is broadly drawn to a nucleic acid complementary to SEQ ID NO:1. It is noted that polynucleotides comprising as few as one nucleic acid complementary to SEQ ID NO:1 are "complementary" to SEQ ID NO:1. Claim 4 is drawn to nucleic acids capable of hybridizing to a nucleic acid comprising SEQ ID NO:1. Claims 5-6 encompass nucleic acids comprising a partial length of SEQ ID NO:1, a nucleic acid complementary to nucleic acids comprising a partial length of SEQ ID NO:1, nucleic acids capable of hybridizing under stringent conditions to a nucleic acid comprising a partial or the full length of SEQ ID NO:1, and nucleic acids complementary to nucleic acids capable of hybridizing under stringent conditions to a nucleic acid comprising a partial or the full length of SEQ ID NO:1. Claim 7 is drawn to a diagnostic agent for stage 4s neuroblastoma comprising as the active ingredient: nucleic acids comprising a partial length of SEQ ID NO:1, a nucleic acid complementary to nucleic acids comprising a partial length of SEQ ID NO:1, nucleic acids capable of hybridizing under stringent conditions to a nucleic acid comprising a partial or the full length of SEQ ID NO:1, or nucleic acids complementary to nucleic acids capable of hybridizing under stringent conditions to a nucleic acid comprising a partial or the full length of SEQ ID

NO:1. Claims 8-9 are drawn to a primer containing a DNA complementary to SEQ ID NO:175, a DNA complementary to SEQ ID NO:176, a DNA capable of hybridizing under stringent conditions to a DNA complementary to SEQ ID NO:175, and a DNA capable of hybridizing under stringent conditions to a DNA complementary to SEQ ID NO:176. It is noted that polynucleotides comprising as few as one nucleic acid complementary to SEQ ID NO:175 or 176 is "complementary" to SEQ ID NO:175 or SEQ ID NO:176, in particular. Further, as SEQ ID NO:175 and SEQ ID NO:176 comprise at least one of each possible nucleic acid, every polynucleotide imaginable is complementary to SEQ ID NO:175 and SEQ ID NO:176. Claim 14 is drawn to a nucleic acid capable of hybridizing to a nucleic acid complementary to SEQ ID NO:1.

Wang et al teaches a polynucleotide, SEQ ID NO:769963, that is 99.7% identical to a 615 base pair segment that is a partial length of instant SEQ ID NO:1 that would hybridize under stringent conditions to a nucleic acid complementary to SEQ ID NO:1 (see below). Further, SEQ ID NO:769963 is complementary to SEQ ID NOs:175-176 and is capable of hybridizing under stringent conditions to DNA complementary to SEQ ID NOs:175-176.

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Query Match             39.0%;  Score 613;  DB 7;  Length 615;
  Best Local Similarity   99.7%;  Pred. No. 3.5e-117;
  Matches  613;  Conservative    1;  Mismatches    1;  Indels    0;  Gaps
0;

Qy         498 TTAGATCACTCATTTAAAATCTGAAGAAGTCAAATTATTTTTTATAAAGATCCAGAATAA
557
               ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         615 TTAGATCACTCATTTAAAATCTGAAGAAGTCAAATTATTTTTTATAAAGATCCAGAATAA
556

Qy         558 TAGTGTATGTATTTCTAAATAATCTGAATATGTTTACATTGGTTTTTTTTTTTTAAACCT
617
               ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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Db        555 TAGTGTATGTATTTCTAAATAATCTGAATATGTTTACATTGGTTTTTTTTTTTTAAACCT
496

Qy        618 AGGCTAGGAAGGGATTACCTATTATCTAACAAACATAGTGCAACTGTATAGATAAGGGGC
677

            |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        495 AGGCTAGGAAGGGATTACCTATTATCTAACAAACATAGTGCAACTGTATAGATAAGGGGC
436

Qy        678 AAACTTCAAAGATTGGATATTGTTTATTATGTGAAAGATACATAGGTCTGGCTATGATTT
737

            |||||||||||||||||||||||||||||||||||||||||||||||||||:||||||||||
Db        435 AAACTTCAAAGATTGGATATTGTTTATTATGTGAAAGATACATAGGTCTKGCTATGATTT
376

Qy        738 GGAAGTCCTAGGTAACTGGTTAGGCTTTTCAGGATTGACAGCAGCTGTGCAGAAATTTTG
797

            |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        375 GGAAGTCCTAGGTAACTGGTTAGGCTTTTCAGGATTGACAGCAGCTGTGCAGAAATTTTG
316

Qy        798 TTAAATGCTTATCATTTTAAAAAGCTGTATTCAAAATATTTCTAATTTTCACTATTTTTT
857

            |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        315 TTAAATGCTTATCATTTTAAAAAGCTGTATTCAAAATATTTCTAATTTTCACTATTTTTT
256

Qy        858 AATGTAAATGTTTTTGAGAGTCAAAGAAGATTCTATACTTTTACTTATGAAGCAGTTTGT
917

            |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        255 AATGTAAATGTTTTTGAGAGTCAAAGAAGATTCTATACTTTTACTTATGAAGCAGTTTGT
196

Qy        918 TGTTGTTTGTTCATTTCTTTTTTTGGTATGGGGTCTTTCTCTGTTGCCCAAGGCCGGAGT
977

            |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        195 TGTTGTTTGTTCATTTCTTTTTTTGGTATGGGGTCTTTCTCTGTTGCCCAAGGCCGGAGT
136

Qy        978 ATGTAGTGGTGCAATCACAGCTCGCTGCAGGCTTAAACTCCTGGTCTCAAGCCATTTTTC
1037

            |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        135 ATGTAGTGGTGCAATCACAGCTCGCTGCAGGCTTAAACTCCTGGTCTCAAGCCATTTTTC 76

Qy       1038 TGCCTCAGCCTTTCTAGTAGCTGGGAGTACAGGCAAATGCTACTGCCCCAAGCTAATTTA
1097

            | ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         75 TACCTCAGCCTTTCTAGTAGCTGGGAGTACAGGCAAATGCTACTGCCCCAAGCTAATTTA 16

Qy       1098 TGTTTTATTTTTATT 1112
                ||||||||||||||||
Db         15 TGTTTTATTTTTATT 1
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Wang et al further teaches a probe consisting of a complement to SEQ ID NO:769963 (see claim 1 of Wang et al, in particular) that would hybridize to instant SEQ ID NO:1 under stringent conditions. Further, it is noted that claim 7 appears to contain statements reciting purpose or intended use. It is noted that statements of intended purposes or uses are not considered limitations because they merely state an intended use of the invention rather than any distinct definition of any of the claimed invention's limitations (see Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999)). Thus, recitation of statements describing the claimed product as an active ingredient of a diagnostic agent for stage 4s neuroblastoma are not given patentable weight and are not limitations to the claims.

Summary

No claim is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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